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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,540	03/08/2001	Adrian Bot	A30571-A-PCT/USA-A	7183

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,540

Applicant(s)

BOT ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 24/b6
4w
- 1) ☒ Responsive to communication(s) filed on 8/29/2005.
2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 1 and 2 is/are allowed.
6) ☒ Claim(s) 3 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on August 29, 2005 has been entered.

DETAILED ACTION

This application filed March 8, 2001 is a continuation-in-part of application 09/308,511 filed May 19, 1999, which is a 371 national stage filing of PCT/US97/21687, filed November 21, 1997, which claims priority to application 08/755,034, filed November 22, 1996, now patent 6,204,250.

Applicants amendment filed August 29, 2005 has been received and entered. The specification has been amended.

Note that the after final amendment filed December 9, 2004 was not entered. See advisory action and document scanned June 6, 2005. The request for continued examination of the application did not request that this amendment be entered.

Claims 1-3 are pending and currently under examination.

Priority

The priority claim filed on August 29, 2005 has been entered and granted. See petition decision mailed October 3, 2005.

Claim Rejections - 35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, an “immunogenic composition” is now being claimed however the only structural component of the composition specifically recited is a nucleic acid. It is noted that it can encode antigens that by definition should be immunogenic, however the nucleic acid itself does not appear to be immunogenic. More clearly setting forth what is immunogenic and specific means in which it “may be used” would address the basis of the rejection.

No arguments are presented by applicants, so the rejections are maintained for the reasons of record.

Claim Rejections - 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3 rejected under 35 U.S.C. 102(b) as being anticipated by Bot *et al.* is withdrawn.

The claim for priority has been granted and the effective filing date is now November 22, 1996. Bot *et al.* was published December of 1996, thus fails to qualify as a 102 type reference.

Claim 3 stands rejected under 35 U.S.C. 102(b) as being anticipated by Lai *et al.*

Claim 3 stands rejected under 35 U.S.C. 102(b) as being anticipated by Assateerawatt *et al.* (1993).

Claim 3 stands rejected under 35 U.S.C. 102(b) as being anticipated by del Canho *et al.*

No arguments are presented by applicants, so the rejections are maintained for the reasons of record.

It is noted that Applicants have argued that by Lai *et al.*, Assateerawatt *et al.* (1993) and del Canho *et al.* each teach methods of vaccination wherein a recombinant protein is administered, not the DNA used to make the recombinant protein, and Applicants arguments were found persuasive for method claims 1 and 2. However, as acknowledged in Applicants' arguments, the references do teach a recombinant polynucleotide capable of encoding the antigens.. Since each Lai *et al.*, Assateerawatt *et al.* (1993) and del Canho *et al.* teach the use of recombinant proteins made of recombinant DNA technology, the vectors "*may be used* in a

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method of inducing a cellular immune response” (*emphasis added* claim 3) as evidenced by the cited references. In this case it was used to generate the protein used in the vaccine.

Conclusion

Claims 1 and 2 are allowed. DNA vaccines were known at the time of filing (see for example Donnelly *et al.* 1994 (IDS reference)), and experiments demonstrated that nucleic acids encoding antigens could be administered as vaccines (see Donnelly *et al.* figure 1 for example (IDS reference)). However, while the technique was demonstrated to be affective in adults, what was not demonstrated was that the technique could be extended to infants.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Woitach
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